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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/669,869	09/23/2003	Cyrus Rustam Kumana	V9661.0072	5138
32172 75	590 03/20/2006		EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE)			CHOI, FRANK I	
1177 AVENUE 41 ST FL.	OF THE AMERICAS (6	IH AVENUE)	ART UNIT	PAPER NUMBER
NEW YORK,	NY 10036-2714		1616	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/669,869	KUMANA ET AL.				
Office Action Summary	Examiner	Art Unit				
	Frank I. Choi	1616				
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet	with the correspondence ac	ldress			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA.  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period vortice. Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUN 36(a). In no event, however, may a vill apply and will expire SIX (6) MO , cause the application to become	IICATION. a reply be timely filed  ONTHS from the mailing date of this canada and the mailing date of this canada and the cana				
Status						
1) Responsive to communication(s) filed on						
·— ·	action is non-final.					
•	<del></del>					
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.	.D. 11, 453 O.G. 213.				
Disposition of Claims						
4) Claim(s) 1-42 is/are pending in the application.						
4a) Of the above claim(s) is/are withdraw	wn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-42</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examine	r.					
10)⊠ The drawing(s) filed on 23 September 2003 is/a	are: a)□ accepted or b)	⊠ objected to by the Exa	miner.			
Applicant may not request that any objection to the	drawing(s) be held in abey	ance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct			• •			
11)☐ The oath or declaration is objected to by the Ex	caminer. Note the attach	ed Office Action or form P	TO-152.			
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C.	§ 119(a)-(d) or (f).				
1. Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents	s have been received in	Application No				
<ol><li>Copies of the certified copies of the prior</li></ol>	rity documents have bee	n received in this National	Stage			
application from the International Bureau	u (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list	of the certified copies no	ot received.				
			•			
Attachment(s)						
1) Notice of References Cited (PTO-892)  Discrete Transfer (PTO-948)		y Summary (PTO-413) o(s)/Mail Date				
<ul> <li>2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ul>		f Informal Patent Application (PTC	O-152)			

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#### **DETAILED ACTION**

## **Drawings**

The drawings are objected to because 37 CFR 1.84(u)(1) indicates that the abbreviation "Fig." be used instead of "Figure". Further the graphs in Figure 2 are too small such that the numbers on the x and y axis are not legible. See 37 CFR 1.84(p)(3) (letters, numbers and reference characters must be at least .32 cm (1/8 in.) in height). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### Specification

The disclosure is objected to because of the following informalities: Pg. 6, "<u>FIGURES</u>" should be "BRIEF DESCRIPTION OF THE DRAWINGS".

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Appropriate correction is required.

## Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,6,7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/24029.

WO 99/24029 expressly discloses a composition containing arsenic trioxide, water, NaOH and HCl (Pg. 27, lines 20-38).

Claims 1-3,7,8 are rejected under 35 U.S.C. 102(a) as being anticipated by CN1370540 (Abstract).

CN1370540 (Abstract) expressly discloses a composition containing arsenic trioxide, water, NaOH and HCl.

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24029 or CN1370540.

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WO 99/24029 or CN1370540 disclose treatment of leukemia with neutralized solution containing arsenic trioxide, NaOH and HCl (WO 99/24029, see entire document, especially, Pg. 14, lines 18-38, Pgs. 15-41, Claims 16-18; CN1370540, Abstract).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using specified amounts of arsenic trioxide, water, HCl and NaOH and specific method of preparation. However, the prior art discloses similar solutions which are used for treatment of leukemia having a neutralized pH and containing NaOH and HCl. As such, it would have been well within the skill in the art to very the steps and concentrations of NaOH and HCl added so long as the final solution is at neutralized pH, with the expectation the final solution would be suitable in the treatment of leukemia. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). See also In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003)("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re

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Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). See also Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

#### Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pairdirect.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC March 16, 2006

Joh Ulu